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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,144	03/05/2002	Victor Markowitz	4009US (43413-276314)	7128

23370 7590 06/30/2004

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EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/090,144

Applicant(s)

MARKOWITZ ET AL.

Examiner

Channing S Mahatan

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/13/02 & 3/06/03.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

ART UNIT DESIGNATION

The Group and/or Art Unit designated for this application has changed. Applicants are hereby informed that future correspondence regarding this application should be directed to Group Art Unit 1631.

Claims Under Examination

Claims herein under examination are claims 1-21.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claim 1 and all claims dependent therefrom are indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble. The preamble states that it is "A method of analyzing gene expression, gene annotation, and sample information in a relational format supporting efficient exploration and analysis", however the claim recites a final step of "displaying the results of said correlation". While minor details are not required in method/process claims, at least the basic step must be recited in a positive, active fashion. The claim does not set forth the conditions/state when "gene expression, gene annotation, and sample information in a relational format" are analyzed. Rather, it is noted the

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instant claims provide for the steps “determining the level of gene expression of one or more DNA fragments” and “correlating the level of gene expression with the clinical database and fragment index”. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

Claims 1, 8, 15, and all claims dependent therefrom recite the step “receiving a query regarding gene expression of one or more DNA fragments” which is vague and indefinite. It is unclear what information the “query” is being received. For example, is the “query” a numerical value (i.e. expression level), gene name, some arbitrary symbol, etc. Applicants’ can resolve this issue by particularly pointing out what form/format the query is. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

Claims 4, 11, and 18 recite the language “consistently expressed within the sample set, and those that are consistently not expressed” which is vague and indefinite. The term “consistently” implies some range of values or criteria(s) that establishes a level of consistency among DNA fragment expression data; thereby distinguishing it from DNA fragment expression that is not considered to be consistently expressed. Applicants’ can resolve this issue by particularly pointing out what is defines consistent expression within the sample set and consistent non-expression. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 5, 12, and 19 are vague and indefinite with respect to “gene set” and “absent gene set”. It is unclear the criteria(s) defining a “gene set”/“absent gene set” for the “first signature” and the “second signature”. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 15 recites the limitation “fragment S index” which is vague and indefinite. It is unclear what Applicants’ regard this limitation to encompass since it appears that no definition for said limitation is found. The specification indicates a “fragment index” is defined as “a comprehensive database of biological properties (annotations) for all fragments (full-length genes and EST’s)” (page 30, lines 2-3). However, it is unclear if this is a typographical error or some specific fragment index. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Basset et al.

(Gene expression informatics – it’s all in your mine. Nature Genetics Supplement. January 1999. Volume 21, page 51-55).

Bassett et al. reviews the technical and intellectual issues involved in the data processing, storing and retrieving, and analysis of gene expression information (page 51, left column, lines 37-41). Figure 1 depicts an overview of the information system for large-scale genome expression experiments, wherein physical array devices are connected/networked with data management warehouses (i.e. relational database such as star or snowflake) and interfaced with the web to provide image analysis, results & summaries, links to other databases, and accessibility to other applications (page 51, right column, lines 3-5; and page 52). Of central

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importance to Bassett et al. is a unified infrastructure for collecting, storing, retrieving and querying data for the optimal utilization of gene expression data, and the authors outline the construction and essential information of such a data warehouse (pages 53-54, beginning on the left column, line 1). The authors outline particular steps and requirements for the construction of the data warehouse. Particularly, that the “data in the warehouse The authors indicate integration of experimental data with external information resources (i.e. Entrez) thereby allowing one to explore (i.e. query) the different resource nodes and to select the ‘most important records by user-defined or default criteria and then to summarize these results in a condensed overview of the findings relevant to genes that are upregulated or downregulated (or both) (page 54, beginning on the left column, line 56). Finally, Bassett et al. describe critical aspects of the visualization/display of the genome wide expression data and state current examples of graphical displays to provide snapshots or overviews said expression data (i.e. on-line analytic processing). Thus, Bassett et al. anticipates the claimed invention.

EXAMINER COMMENT

The term “E northern analysis” is understood to be referring to following from the specification:

“Electronic northern tool analysis determines the ranges of expression values of genes and EST's across all tissue types represented in the DW 222. More particularly, a user-defined gene set and one or more samples sets are used to report the range of expression levels for each gene fragment in the gene set across each sample set, for all the samples where the fragment is called present. The range is reported using upper and lower percentile levels specified by the user. For example, if the user chooses 100% and 0% as the upper and lower percentile levels, the analysis reports the maximum and minimum range of expression levels for all present calls.” (page 14, lines 5-11)
“Electronic Northern Analysis (E Northern) which takes a user-defined gene set and one or more sample sets as input and reports the range of expression levels for each gene fragment in the gene set across each sample set, for all of the samples with user-specified present/absent calls.” (page 69, lines 10-13)

OBJECTION OF DISCLOSURE

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains embedded hyperlinks and/or other form of browser-executable code; for example, page 6, line 19; page 15, line 3; page 19, line 15, 17, and 19. Applicants are required to delete the embedded hyperlinks and/or other form of browser-executable code. Applicants are requested to review the application for embedded hyperlinks and/or other forms of browser-executable code and delete them. Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference. See M.P.E.P. § 608.01 and 608.01(p). Applicants are to note a “www” format will yield an executable hyperlink, thus, a suggested format is “World Wide Web”.

Appropriate correction is required.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent Applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify Applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables Applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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Date: *June 25, 2004*
Examiner Initials: *CSM*

MPW
MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
6/28/04